List of substances	Limitations (residue and limits of addition expressed as percent by weight of finished packaging cellophane)
Tetrahydrofuran	Residue limit of 0.1 percent.
Titanium dioxide .	
Toluene	Residue limit of 0.1 percent.
Toluene sulfonamide formaldehyde	0.6 percent as the basic polymer.
Triethylene glycol .	
Triethylene glycol diacetate, prepared from triethylene glycol containing not more than 0.1 percent of diethylene glycol .	
2,2,4-Trimethyl-1,3 pentanediol diisobutyrate	For use only in cellophane coatings and limited to use at a level not to exceed 10 percent by weight of the coating solids except when used as provided in § 178.3740 of this chapter
Urea (carbamide) .	
Urea formaldehyde	As the basic polymer.
Urea formaldehyde modified with methanol, ethanol, butanol diethylenetriamine, triethylenetetramine, tetraethylenepentamine, guanidine, sodium sulfite, sulfanilic acid, imino-bis-ethylamine, imino-bis-propylamine, imino-bis-butylamine, diaminopropane, diaminobutane, aminomethylsulfonic acid, polyamines made by reacting ethylenediamine or trimethylenediamine with dichlorethane or dichloropropane .	As the basic polymer, and used as a resin to anchor coatings to the substrate.
Vinyl acetate-vinyl chloride copolymer resins	As the basic polymer.
Vinyl acetate-vinyl chloride-maleic acid copolymer resins	Do.
Vinylidene chloride copolymerized with one or more of the following: Acrylic acid, acrylonitrile, butyl acrylate, butyl methacrylate, ethyl acrylate, 2-ethylhexyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, itaconic acid, methacrylic acid, methyl acrylate, methyl methacrylate, propyl acrylate, propyl methacrylate, vinyl chloride .	Do.
Vinylidene chloride-methacrylate decyloctyl copolymer	Do.
Wax, petroleum, complying with § 178.3710 of this chapter .	

(d) Any optional component listed in this section covered by a specific food additive regulation must meet any specifications in that regulation.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11842, Mar. 19, 1982; 64 FR 57978, Oct. 28, 1999]

§ 177.1210 Closures with sealing gaskets for food containers.

Closures with sealing gaskets may be safely used on containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) Closures for food containers are manufactured from substances generally recognized as safe for contact with food; substances that are subject to the provisions of prior sanctions; substances authorized by regulations in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter; and closure-sealing gaskets, as further prescribed in this section.

(b) Closure-sealing gaskets and overall discs are formulated from substances identified in § 175.300(b) of this chapter, with the exception of paragraph (b)(3) (v), (xxxi), and (xxxii) of that section, and from other optional substances, including the following:

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval within the meaning of section 201(s) of the act.

(3) Substances that are the subject of regulations in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter and used in accordance with the conditions prescribed.

(4) Substances identified in paragraph (b)(5) of this section, used in amounts not to exceed those required to accomplish the intended physical or technical effect and in conformance with any limitation provided; and further provided that any substance employed in the production of closure-sealing gasket compositions that is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with the identity or specifications prescribed.

(5) Substances that may be employed in the manufacture of closure-sealing gaskets include:

TABLE 1

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Arachidyl-behenyl amide (C_{20}–C_{22}fatty acid amides)	5 percent.
Azodicarbonamide	1. 2 percent. 2. 5 percent; for use only in the manufacture of polyethylene complying with item 2.1 in § 177.1520(c) of this chapter.
Balata rubber .	
Benzyl alcohol	1 percent.
Brominated isobutylene-isoprene copolymers, produced when isobutylene-isoprene copolymers complying with § 177.1420(a)(2) are modified by bromination with not more than 2.3 weight-percent of bromine and having a Mooney Viscosity (ML 1+8 (125 °C)) of 27 or higher. The viscosity is determined by the American Society for Testing and Materials (ASTM) method D 1646–81, ''Standard Test Method for Rubber—Viscosity and Vulcanization Characteristics (Mooney Viscometer),'' which is incorporated by reference in accordance with 5 U.S.C. 522(a) and 1 CFR part 51. Copies are available from the Association of Official Analytical Chemists International, 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2504 and the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC .	
1,3-Butanediol .	
Calcium tin stearate	2 percent.
Calcium zinc stearate	Do.
Carbon, activated	1 percent.
Castor oil, hydrogenated	2 percent.
Chlorinated isobutylene-isoprene copolymers complying with § 177.1420.	
Coco amide (coconut oil fatty acids amides)	2 percent.
Cork (cleaned, granulated) .	
Diebenzamide phenyl disulfide	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Di(C_7, C_9-alkyl) adipate	Complying with § 178.3740 of this chapter; except that, there is no limitation on polymer thickness.
Di-2-ethylhexyl adipate .	
Di-2-ethylhexyl sebacate	2 percent.
Di-2-ethylhexyl terephthalate (CAS Reg. No. 006422–86–2).	For use as a plasticizer at levels not exceeding 75 parts per hundred by weight of permitted vinyl chloride homo- and/or copolymer resins used in contact with food of Types I, II, IV–B, VI–A, VI–B, VI–C (up to 15 percent alcohol by volume), VII–B, and VIII described in § 176.170(c) of this chapter, table 1, and under conditions of use A through H described in § 176. 170 (c) of this chapter, table 2.
Dihexyl ester of sodium sulfosuccinate	1 percent.
Diisodecyl phthalate	No limitation on amount used but for use only in closure-sealing gasket compositions used in contact with non-fatty foods containing no more than 8 percent of alcohol.
Di-β-naphthyl-*p*-phenylenediamine	1 percent.
Dipentamethylenethiurametetrasulfide	0.4 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Eicosane (technical grade) (water-white mixture of predominantly straight-chain paraffin hydrocarbons averaging 20 carbon atoms per molecule) .	
Epoxidized linseed oil .	
Epoxidized linseed oil modified with trimellitic anhydride .	
Epoxidized safflower oil .	
Epoxidized safflower oil modified with trimellitic anhydride .	
Epoxidized soybean oil modified with trimellitic anhydride .	
Erucylamide	5 percent.
Ethylene-propylene copolymer .	

TABLE 1—Continued

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Ethylene-propylene modified copolymer elastomers produced when ethylene and propylene are copolymerized with 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene. The finished copolymer elastomers so produced shall contain not more than 5 weight-percent of total polymer units derived from 5-methylene-2-norbornene and/or 5-ethylidine-2-norbornene, and shall have a minimum viscosity average molecular weight of 120,000 as determined by the method described in § 177.1520(d)(5), and a minimum Mooney viscosity of 35 as determined by the method described in § 177.1520(d)(6) .	
Ethylene-vinyl acetate copolymer .	
Glyceryl mono-12-hydroxystearate (hydrogenated glyceryl ricinoleate) .	2 percent.
Gutta-percha .	
Hexamethylenetetramine	1 percent.
Hexylene glycol	0.5 percent.
Isobutylene-isoprene copolymers complying with § 177.1420.	
Maleic anhydride-polyethylene copolymer	5 percent.
Maleic anhydride-styrene copolymer	Do.
2,2′-Methylenebis[6-(1-methylcylcohexyl)-*p*-cresol]	1 percent.
Mixed octylated diphenylamine (CAS Reg. No. 68411–46–1)	0.1 percent in isobutylene-isoprene and chlorinated isobutylene-isoprene copolymers complying with § 177.1420, and brominated isobutylene-isoprene copolymers complying with this section.
Napthalene sulfonic acid-formaldehyde condensate, sodium salt .	0.2 percent.
Natural rubber (crepe, latex, mechanical dispersions) .	
α-*cis*-9-Octadecenyl-*omega*-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly (oxyethylene) content averages 20 moles .	0.5 percent.
Oleyl alcohol	1 percent.
4,4′-Oxybis (benzene sulfonyl hydrazide)	0.5 percent.
Paraformaldehyde	1 percent.
Polybutadiene .	
Poly-*p*-dinitroso benzene (activator for butyl rubber)	1 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.
Polyethylene glycol 400 esters of fatty acids derived from animal and vegetable fats and oils .	1 percent.
Polyisobutylene complying with § 177.1420.	
Polyoxypropylene-polyoxyethylene condensate, average mol. wt. 2750–3000.	0.05 percent.
Polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid (CAS Reg. No. 26375–23–5). .	For use only: No limitation on amount used, but for use only in closure gasket compositions used in contact with food types VI–A and VI–C (up to 15 percent alcohol) under conditions of use D, E, F, and G, as described in § 176.170(c) of this chapter, tables 1 and 2, respectively.
Potassium benzoate	1 percent.
Potassium perchlorate	Do.
Potassium propionate	2 percent.
Potassium and sodium persulfate	1 percent.
Resorcinol	0.24 percent; for use only as a reactive adjuvant substance employed in the production of gelatin-bonded cord compositions for use in lining crown closures. The gelatin so used shall be technical grade or better.
Rosins and rosin derivatives as defined in § 175.300(b)(3)(v) of this chapter for use only in resinous and polymeric coatings on metal substrates; for all other uses as defined in § 178.3870 of this chapter .	
Sodium cetyl sulfate	1 percent.
Sodium decylbenzenesulfonate	Do.
Sodium decyl sulfate	Do.
Sodium formaldehyde sulfoxylate	0.05 percent.
Sodium lauryl sulfate	1 percent.
Sodium lignin sulfonate	0.2 percent.
Sodium myristyl sulfate (sodium tetradecyl sulfate)	0.6 percent.
Sodium nitrite	0.2 percent; for use only in annular ring gaskets applied in aqueous dispersions to closures for containers having a capacity of not less than 5 gallons.
Sodium *o*-phenylphenate	0.05 percent.

TABLE 1—Continued

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Sodium polyacrylate	5 percent.
Sodium and potassium pentachlorophenate	0.05 percent.
Sodium salt of trisopropyl napthalenesulfonic acid	0.2 percent.
Sodium tridecylsulfate	0.6 percent.
Stearic acid amide	5 percent.
Sulfur	For use only as a vulcanizing agent in vulcanized natural or synthetic rubber gasket compositions at a level not to exceed 4 percent by weight of the elastomer content of the rubber gasket composition.
Tallow, sulfated	1 percent.
Tin-zinc stearate	2 percent.
Tri(mixed mono- and dinonylphenyl) phosphite	1 percent.
Vinyl chloride-vinyl stearate copolymer .	
Zinc dibutyldithiocarbamate	0.8 percent; for use only in vulcanized natural or synthetic rubber gasket compositions.

TABLE 2—MAXIMUM EXTRACTIVES TOLERANCES

[In parts per million]

Type of closure-sealing gasket composition	Chloroform fraction of water extractives	Chloroform fraction of heptane extractives	Chloroform fraction of alcohol extractives
1. Plasticized polymers, including unvulcanized or vulcanized or otherwise cured natural and synthetic rubber formed in place as overall discs or annular rings from a hot melt, solution, plastisol, organisol, mechanical dispersion, or latex	50	500	50
2. Preformed overall discs or annular rings of plasticized polymers, including unvulcanized natural or synthetic rubber	50	250	50
3. Preformed overall discs or annular rings of vulcanized plasticized polymers, including natural or synthetic rubber	50	50	50
4. Preformed overall discs or annular rings of polymeric or resinous-coated paper, paperboard, plastic, or metal foil substrates	50	250	50
5. Closures with sealing gaskets or sealing compositions as described in 1, 2, 3, and 4, and including paper, paperboard, and glassine used for dry foods only	(1)	(1)	(1)

[1] Extractability tests not applicable.

(c) The closure assembly to include the sealing gasket or sealing compound, together with any polymeric or resinous coating, film, foil, natural cork, or glass that forms a part of the food-contact surface of the assembly, when extracted on a suitable glass container with a solvent or solvents characterizing the type of foods, and under conditions of time and temperature characterizing the conditions of its use as determined from tables 3 and 4 shall yield net chloroform-soluble extractives (corrected for zinc as zinc oleate) not to exceed the tolerances specified in table 2, calculated on the basis of the water capacity of the container on which the closure is to be used. Employ the analytical method described in §175.300 of this chapter, adapting the procedural details to make the method applicable to closures; such as, for example, placing the closed glass container on its side to assure contact of the closure's food-contacting surface with the solvent.

TABLE 3—TYPES OF FOOD

I. Nonacid (pH above 5.0), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
II. Acidic (pH 5.0 or below), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
IV. Dairy products and modifications:
  A. Water-in-oil emulsions, high- or low-fat.
  B. Oil-in-water emulsions, high- or low-fat.
V. Low-moisture fats and oils.
VI. Beverages:
  A. Containing alcohol.
  B. Nonalcoholic.
VII. Bakery products.
VIII. Dry solids (no end-test required).

TABLE 4—TEST PROCEDURES WITH TIME-TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM CLOSURE-SEALING GASKETS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Conditions of use	Types of food (see table 3)	Extractant		
		Water	Heptane [2]	8 percent alcohol
A. High temperature heat-sterilized (e.g., over 212 °F) .	I, IV–B	250 °F, 2 hr	.....	
	III, IV–A, VII	.....do	150 °F, 2 hr .	
B. Boiling water-sterilized	II	212 °F, 30 min	.....	
	III, VII	.....do	120 °F, 30 min .	
C. Hot filled or pasteurized above 150 °F .	II, IV–B	Fill boiling, cool to	.	
	III, IV–A	100 °F .	120 °F, 15 min .	
	V	.....do	.....do .	
D. Hot filled or pasteurized below 150 °F .	II, IV–B, VI–B	150 °F, 2 hr	.....	
	III, IV–A	.....do	100 °F, 30 min .	150 °F, 2 hr
	V		.....do	
	VI–A			
E. Temperature filled and stored (no thermal treatment in the container) .	II, IV–B, VI–B	120 °F, 24 hr	.....	
	III, IV–A	.....do	70 °F, 30 min .	120 °F, 24 hr.
	V		.....do	
	VI–A			
F. Refrigerated storage (no thermal treatment) .	I, II, III, IV–A, IV–B, VI–B, VII .	70 °F, 48 hr	70 °F, 30 min	70 °F, 48 hr.
	VI–A			
G. Frozen storage (no thermal treatment in the container) .	I, II, III, IV–B, VII ...	70 °F, 24 hr	.	

[1] Heptane extractant not applicable to closure-sealing gaskets overcoated with wax.
[2] Time and temperature.

[42 FR 14572, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 47 FR 22090, May 21, 1982; 49 FR 5748, Feb. 15, 1984; 55 FR 34555, Aug. 23, 1990; 61 FR 14480, Apr. 2, 1996; 65 FR 26745, May 9, 2000; 65 FR 52908, Aug. 31, 2000]

§ 177.1211 Cross-linked polyacrylate copolymers.

Cross-linked polyacrylate copolymers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) *Identity*. For the purpose of this section, the cross-linked polyacrylate copolymers consist of:

(1) The grafted copolymer of cross-linked sodium polyacrylate identified as 2-propenoic acid, polymers with *N*,*N*-di-2-propenyl-2-propen-1-amine and hydrolyzed polyvinyl acetate, sodium salts, graft (CAS Reg. No. 166164–74–5); or

(2) 2-propenoic acid, polymer with 2-ethyl-2-(((1-oxo-2-propenyl)oxy)methyl)-1,3-propanediyl di-2-propenoate and sodium 2-propenoate (CAS Reg. No. 76774–25–9).

(b) *Adjuvants*. The copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such copolymers. The optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Extractives limitations*. The copolymers identified in paragraph (a) of this section, in the finished form in which they will contact food, must yield low molecular weight (less than 1,000 Daltons) extractives of no more than 0.15 percent by weight of the total polymer when extracted with 0.2 percent by weight of aqueous sodium chloride solution at 20 °C for 24 hours. The low molecular weight extractives shall be determined using size exclusion chromatography or an equivalent method. When conducting the extraction test, the copolymer, with no other absorptive media, shall be confined either in a finished absorbent pad or in any suitable flexible porous article, (such as a ''tea bag'' or infuser), under an applied pressure of 0.15 pounds per square inch (for example, a 4x6 inch square pad is subjected to a 1.6 kilograms applied mass). The solvent used shall be at